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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,598	07/03/2006	Ashlee Moses	899-76557-05	8948

24197 7590 01/24/2008
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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,598	MOSES ET AL.	
	Examiner	Art Unit	
	Nicole Kinsey White, PhD	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-24 and 37-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-24 and 37-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election without traverse of Group III (claims 14-24 and new claims 37-44) in the reply filed on November 12, 2007 is acknowledged. In a telephonic interview on January 8, 2008, applicants' representative, Susan Alpert Siegel, further elected SEQ ID NO:1 (RDC1) in response to a species election.

The species election was made because SEQ ID NOs:1, 3, 5, 7, 9, 11, 13, 25, 27 and 29, corresponding to RDC-1, IGFBP2, FLJ14103, KIAA0367, Neuritin, INSR, KIT (c-kit), LOX, NOV and ANGPTL2, respectively, each have a different structure and/or function and therefore lack the same or corresponding special technical feature. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Because the recited species do not have a common property or activity **and** do not have a common structure, the requirement for a shared technical feature has not been met.

Claims

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 40-45 have been renumbered 39-44. The dependencies have been renumbered as well. A compliant claim listing is required in applicants' next response.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-24 and 37-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37 and 38 are dependent upon a canceled claim. Therefore, there is insufficient antecedent basis for the limitations recited in claims 37 and 38. For examination purposes, it is assumed that claims 37 and 38 depend from claim 14.

Claims 14, 18, 19, 20, 22, 23, 40 and 41 recite "specific for" or "specific to." It is not clear what this means. The antisense, siRNA, small molecule inhibitor, antibody or ribozyme is "specific for" or "specific to" a sequence or protein in what way (binding,

inhibiting, etc.)? The metes and bounds of the claims cannot be determined without further clarification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 15 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Moses et al. (Ann. N.Y. Acad. Sci., 2002, 975:180-191).

The claims are drawn to, *inter alia*, a method of inhibiting at least one of: Kaposi's sarcoma associated herpesvirus (KSHV)-induced cellular gene expression or encoded biological activity; KSHV infection; or KSHV-mediated effects on cellular proliferation and phenotype, the method comprising introducing into, or expressing within a KSHV-infected human cell at least one of an antisense, siRNA, or ribozyme agent specific for a validated KSHV-induced cellular gene sequence, and in an amount sufficient to inhibit expression of the validated KSHV-induced cellular gene sequence, or contacting the KSHV-infected human cell with a small molecule inhibitor or an antibody specific to protein encoded by the validated KSHV-induced cellular gene, wherein the validated

KSHV-induced cellular gene sequence is a nucleic acid sequence the expression of which is required for the KSHV-induced cellular gene expression or encoded biological activity, the KSHV infection, or the KSHV-mediated effects on cellular proliferation and phenotype, thereby inhibiting at least one of: Kaposi's sarcoma associated herpesvirus (KSHV)-induced cellular gene expression or encoded biological activity; KSHV infection; or KSHV- mediated effects on cellular proliferation and phenotype.

Moses et al. teaches the use of antisense to inhibit the KSHV-induced cellular gene c-kit. Moses et al. found that inhibition of c-Kit activity with the pharmacological inhibitor of c-Kit signaling, STI571, reversed the KSHV-induced morphological transformation of dermal microvascular endothelial cells (DMVEC). Further, the antisense molecules used were phosphorodiamidate morpholino antisense oligomers (PMO-AS). PMO-AS are 15–18 base pair oligonucleotides complementary to a specific mRNA start codon that prevent message translation through steric hindrance. Moses et al. demonstrated that the PMO-AS are efficiently taken up and retained in DMVEC and are effective in reducing expression of the target protein (see pages 187-188).

Claims 14, 15 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Moses et al. (Journal of Virology, 2002, 76(16):8383-8399).

Moses et al. teaches the use of antisense to inhibit the KSHV-induced cellular gene c-kit. Moses et al. found that consistent with increased c-Kit expression, KHSV-infected DMVEC displayed enhanced proliferation in response to the c-Kit ligand, stem cell factor (SCF). Inhibition of c-Kit activity with either a pharmacological inhibitor of c-

Kit (STI 571) or a dominant-negative c-Kit protein reversed SCF-dependent proliferation. Importantly, inhibition of c-Kit signal transduction reversed the KSHV-induced morphological transformation of DMVEC (see, for example, the abstract).

Claims 14, 15 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Luukkonen et al. (WO 02/10339).

Luukkonen et al. teaches the use of PMO antisense to inhibit the KSHV-induced cellular gene c-kit. Luukkonen et al. found that cells treated with the anti-c-kit oligomer did not develop foci but maintained a quiescent contact-inhibited monolayer (see page 28, line 17 to page 29, line 14; Example 2 and Figure 8).

Claims 14, 15 and 20 are rejected under 35 U.S.C. 102(e as being anticipated by Luukkonen et al. (U.S. Patent Application No. 2003/0191048).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Luukkonen et al. teaches the use of PMO antisense to inhibit the KSHV-induced cellular gene c-kit. Luukkonen et al. found that cells treated with the anti-c-kit oligomer

did not develop foci but maintained a quiescent contact-inhibited monolayer (see paragraphs [0104] to [0106];Example 2 and Figure 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-19, 21-24 and 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moses et al. (Ann. N.Y. Acad. Sci., 2002, 975:180-191) or Moses et al. (Journal of Virology, 2002, 76(16):8383-8399) as applied to claims 14, 15 and 20 above, and further in view of GenBank Accession No. AF030297.

The teachings of Moses et al. (Ann. N.Y. Acad. Sci.) and Moses et al. (Journal of Virology) are outlined above.

Neither reference teaches the claimed method where RDC1 is the target of antisense, siRNA, ribozyme or small molecule therapy. However, Moses (Journal of Virology) teaches that RDC1, like c-kit, is upregulated in dermal microvascular endothelial cells (DMVECs) transformed with KSHV (see page 8394, right column).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Moses et al. (Ann. N.Y. Acad. Sci.) or Moses et al. (Journal of Virology) in order to inhibit or treat KSHV infection or KSHV-mediated effects by administering PMO-AS (or other molecules such as siRNA, ribozymes or small molecules) to inhibit the expression or function of RDC1. One would have been motivated to do so given the suggestion by Moses et al. (Journal of Virology) that RDC1 is another cellular gene that is upregulated in KSHV-infected cells. There would have been a reasonable expectation of success given the knowledge that antisense and a small molecule inhibitor were successfully used to inhibit c-kit expression and thus, reversed the KSHV-induced morphological transformation of DMVEC.

As for SEQ ID NO:1 (RDC-1), it is well within the purview of one of ordinary skill in the art to create an antisense, siRNA, ribozyme or small molecule that binds to an RDC-1 sequence or inhibits RDC-1 expression or function, including the RDC-1 of SEQ ID NO:1. For example, see GenBank Accession No. AF030297, where an antisense molecule (instant SEQ ID NO:15) is disclosed for RDC1.

Therefore, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 16-19, 21-24 and 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luukkonen et al. (WO 02/10339) or Luukkonen et al. (U.S. Patent Application No. 2003/0191048) as applied to claims 14, 15 and 20 above, and further in view of GenBank Accession No. AF030297.

The teachings of Luukkonen et al. (WO 02/10339) and Luukkonen et al. (U.S. Patent Application No. 2003/0191048) are outlined above.

Neither reference teaches the claimed method where RDC1 is the target of antisense, siRNA, ribozyme or small molecule therapy. However, both Luukkonen et al. references teach that RDC1, like c-kit, is upregulated in KSHV infected cells (see page 51, lines 4-8, and page 58 of WO 02/10339).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Luukkonen et al. (WO 02/10339) or Luukkonen et al. (U.S. Patent Application No. 2003/0191048) in order to inhibit or treat KSHV infection or KSHV-mediated effects by administering PMO-AS (or other molecules such as siRNA, ribozymes or small molecules) to inhibit the expression or function of RDC1. One would have been motivated to do so given the suggestion by Luukkonen et al. (WO 02/10339) that RDC1 is another cellular gene that is upregulated in KSHV-infected cells. There would have been a reasonable expectation of success given the knowledge that antisense and a small molecule inhibitor were successfully used to inhibit c-kit expression and thus, reversed the KSHV-induced morphological transformation of DMVEC.

As for SEQ ID NO:1 (RDC-1), it is well within the purview of one of ordinary skill in the art to create an antisense, siRNA, ribozyme or small molecule that binds to an RDC-1 sequence or inhibits RDC-1 expression or function, including the RDC-1 of SEQ ID NO:1. For example, see GenBank Accession No. AF030297, where an antisense molecule (instant SEQ ID NO:15) is disclosed for RDC1.

Therefore, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole Kinsey White, PhD whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole Kinsey White, PhD
Examiner
Art Unit 1648

/nkw/

/Stacy B. Chen/ 1-22-2008
Primary Examiner, TC1600